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PATENT 3/12/02
Customer Number 22,852
Attorney Docket No. 1147-0142

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of: U.S. Patent No. 5,750,338	)	
Mark L. Collins et al.	)	Group Art Unit: 1655
Reissue Serial No.: 09/533,906	)	Examiner: D. Johannsen
Reissue Application Filed: March 8, 2000	)	
For: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS	)	

REISSUE LITIGATION BOX
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

NOTICE OF RELATED LITIGATION

The Patent Owner brings to the attention of the Office the following papers from the currently pending litigation between the Patent Owner and Gen-Probe, the Protestor, concerning U.S. Patent No. 5,750,338 (the "'338 patent"), for which reissue is sought by this application. These papers relate to various contentions made by Gen-Probe that the claims of the '338 patent are invalid and unenforceable:

- Gen-Probe's Memorandum of Contentions of Fact and Law ("G-P Contentions");

- Vysis' Memorandum of Contentions of Fact and Law;

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- Expert Report of Mark S. Berninger;

- Expert Report of Fred Kramer and Supplemental Expert Report of Fred Kramer; and

- Expert Report of Andrew P. Feinberg.

The Patent Owner also brings to the attention of the Office the following papers relating to Gen-Probe's motion for partial summary judgment of noninfringement under the doctrine of equivalents and Vysis' request for reconsideration of the Court's prior partial summary judgment of no literal infringement, which were denied by the United States District Court for the Southern District of California:

- Gen-Probe's Notice of Motion and Motion for Partial Summary Judgment of Non-Infringement Under the Doctrine of Equivalents, Memorandum of Points and Authorities in Support Thereof, Declaration of Dr. Kary B. Mullis in Support Thereof, Separate Statement of Undisputed Facts in Support Thereof, and Notice of Lodgment in Support Thereof;

- Vysis' Opposition to Gen-Probe's Motion for Partial Summary Judgment of Noninfringement Under the Doctrine of Equivalents, Declaration of David H Persing in Support Thereof, Declaration of L. Scott Burwell in Support Thereof, Vysis' Statement of Disputed Facts in Opposition, and Notice of Lodgment of Case Authority not in Official Reporter System in Support Thereof;

- Vysis' Supplemental Opposition to Gen-Probe's Motion for Partial Summary Judgment of Noninfringement Under the Doctrine of Equivalents, Supplemental Declaration of L. Scott Burwell in Support Thereof, and Vysis' Supplemental Statement of Disputed Facts in Opposition;

- Gen-Probe's Reply Memorandum of Points and Authorities in Support of its Motion for Partial Summary Judgment of Non-Infringement Under the Doctrine of Equivalents; Reply

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Declaration of Dr. Kary B. Mullis in Support Thereof; Reply Declaration of R. William Bowen in Support Thereof; Reply Separate Statement of Undisputed Facts in Support Thereof, and Reply Notice of Lodgment in Support Thereof; and

- Order Denying (1) Vysis Inc.'s Request for Reconsideration of the Court's June 20, 2001 Order, and (2) Gen-Probe Incorporated's Motion for Partial Summary Judgment of Noninfringement Under the Doctrine of Equivalents.

The Patent Owner also submits the attached Declaration of Dr. Andrew P. Feinberg relating to some of Gen-Probe's invalidity contentions.

REMARKS

I. Gen-Probe's Contention that Claims Encompassing Non-Specific Amplification are Not Enabled

Gen-Probe has asserted that the claims of the '338 patent are not enabled under 35 U.S.C. § 112, ¶ 1. (G-P Contentions, ¶¶ 53-80, 248-268.) That assertion of non-enablement is based on two primary theories: (i) amplification of a target polynucleotide by using random primers is not enabled, and (ii) amplification of a target polynucleotide by using Qβ replicase is not enabled. The Patent Owner urges a full review of paragraphs 53-80 and 248-268 of Gen-Probe's Contentions for a complete recitation of its arguments and for the authority upon which Gen-Probe relies, and a similar review of paragraphs 69-80 and 114-120 of Vysis' Memorandum of Contentions of Fact and Law for a recitation of Vysis' contentions on that issue.

In evaluating this particular allegation, it is noteworthy that the applicants made no claim in their original patent application, in the original patent, or in this reissue application to having invented enzymatic methods for *in vitro* amplification of target polynucleotides. Such techniques were known in the art as of the December 21, 1987 filing date to which this application is entitled. Indeed, PCR was well and widely known as of this date, and many of the specific illustrations of amplification techniques described in the Examples are immediately

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recognizable as variations on the PCR theme. Indeed, it is unquestionably possible to conduct PCR-like reactions in ways that result in either specific amplification of a single sequence or non-specific amplification of a variety of sequences depending on the primers and conditions chosen. (See, e.g., Saiki et al., Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," *Science* 239:487-491 (1988), contrasting PCR with Klenow fragment at 37° C resulting in non-specific priming under non-stringent conditions with PCR using *Taq* polymerase at higher temperature leading to only specific amplification).

Substantial expertise and experimentation was routinely required in order to optimize PCR-like reactions for use in particular cases. The techniques for doing so were well known in the art and need not have been repeated in the specification in order to enable practice of these techniques. In view of the state of the art relating to PCR and other amplification techniques at the time this application was filed, amplification techniques suitable for practicing the claimed invention would have been enabled without any of the further variations on the theme referred to in the Examples. Thus, attacks on specific techniques described in specific Examples do not negate the fact that practice of the claimed invention was otherwise enabled by the state of the art.

The Patent Owner disagrees with Gen-Probe's allegations that claims 1-40 are not enabled. The enablement requirement of 35 U.S.C. § 112, ¶ 1, is met if one of ordinary skill in the art could make and use the invention without undue experimentation. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). Moreover, "[i]t is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification." *Id.* Accordingly, the specification need not expressly teach what is already known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384 ("a patent need not teach, and preferably omits, what is well known in the art"). Inferences based on the skill in the art are thus permissible and can demonstrate enablement. Further, in the biological sciences, a substantial amount of routine experimentation is often required to practice an

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invention, and this is not undue experimentation. *See, e.g., In re Wands*, 858 F.2d 731, 737-740 (Fed. Cir. 1988). Further, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (quotation and citation omitted).

A. Amplification Using Random Primers

Gen-Probe contends that linear and exponential non-specific amplification methods disclosed in Examples 4-6 are not enabled. (G-P Contentions, ¶¶ 56-61, 63-71.) The Patent Owner contends that as of December 21, 1987, a person of ordinary skill in the art would have been able to practice the claimed invention without undue experimentation using techniques similar to those discussed in the Examples. With specific reference to Example 5, one of the methods disclosed employs random primers in conjunction with a DNA polymerase to form double stranded DNA from a target nucleic acid. The example then discloses the use of RNA polymerase lacking sigma subunit to produce many RNA copies of that DNA. To further support its contention that a person of ordinary skill in the art could have practiced the claimed invention using techniques similar to those discussed in Example 5, the Patent Owner relies upon the accompanying Declaration of Andrew P. Feinberg, M.D., the inventor of the random priming procedure for labeling DNA and the co-author of the Feinberg and Vogelstein *Analytical Biochemistry* publication discussed in more detail below.

Example 6 of the '338 patent describes use of the Klenow fragment of DNA polymerase in appropriate buffer with random oligonucleotide primers to bring about non-specific double-stranded DNA synthesis. Example 6 describes what is clearly a variation on the PCR theme involving successive rounds of DNA denaturation, reagent addition, and polymerization to further amplify the DNA. Persons of ordinary skill in the art would have been able to practice the patented invention without undue experimentation using techniques similar to that discussed

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in Example 6 as of December 21, 1987. Indeed, Gen-Probe's contention to the contrary is belied by its earlier argument in the Protest it filed in this reissue application, in which it stated that "[t]he use of random hexamer oligonucleotide primers to initiate non-specific enzymatic reproduction of polynucleotides is disclosed in *Feinberg et al., Anal. Biochem.*132:6-13 (1983)," (Gen-Probe's Protest at 5), and that the Feinberg publication "disclose[s] *in vitro* amplification methods." (Id. at 10.)

The use of random primers for the generation of DNA product, including denaturation conditions, annealing conditions, polymerization conditions, and quantification, is described in the Feinberg publication cited by Gen-Probe in its Protest. It is clear from the description in that publication that there is enormous latitude in the reaction conditions that would permit successful DNA synthesis. These techniques were well known to persons of ordinary skill in the art in December of 1987.

While Feinberg and Vogelstein did not use repeated cycles of thermal denaturation and renaturation to amplify the target nucleic acid, such an approach is disclosed in Example 6 of the '338 patent and also is clearly described in references such as U.S. Patent No. 4,683,202 (July 28, 1987) ("the '202 patent"), which was cited by the PTO during prosecution of the '338 patent and which describes the widely known PCR procedure. The '202 patent describes a variety of reaction conditions that would permit successful amplification of a target nucleic acid using thermal cycling.

While the '202 patent describes conditions for amplification using specific primers, the non-specific primers described in Example 6 could have been used in a manner analogous to the use of specific primers in the '202 patent without undue experimentation.

The optimization of any *in vitro* nucleic acid amplification scheme in December of 1987, even PCR, often required a substantial amount of experimentation. Such experimentation was not undue. *See In re Wands*, 858 F.2d at 737-740. Moreover, it was well understood by those

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skilled in the art that reaction conditions (such as concentration of primers, polymerases, and dNTPs, incubation times and temperatures, pH, and buffer components) could be varied while still achieving amplification of a target nucleic acid. Varying those conditions was considered to be routine by those skilled in the art. Thus, one skilled in the art could have performed the procedures described in the '338 patent of amplification by using random primers without undue experimentation as of December 21, 1987. As further support for the Patent Owner's contention that claims 1-40 are enabled, the Patent Owner relies upon the accompanying Declaration of Andrew P. Feinberg, M.D., the inventor of the random priming procedure for labeling DNA and the co-author of the *Analytical Biochemistry* publication discussed above.

Moreover, the decision of Vysis' predecessor, Gene-Trak, not to commercially pursue an amplification scheme involving random primers relied upon by Gen-Probe has no bearing on the enablement of claims 1-40. Enablement does not require disclosure of a commercializable invention. *See Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1562 (Fed. Cir. 1987), *vacated on other grounds*, 486 U.S. 800 (1988). Gene-Trak intended to pursue a wholly different technology in developing its commercial assays in which the probe, not the target polynucleotide, would be amplified. Although a novice Gene-Trak scientist without a doctor's degree undertook a handful of preliminary amplification experiments using random primers and thermal cycling for purposes of comparison to the intended commercial system, little time and resources were devoted to that endeavor. The limited work of that scientist, who did not have and did not display in the experimental work the requisite level of ordinary skill in this art, simply has no bearing on the enablement issue. While the experimenter's supervisor had a Ph.D. degree, he had no prior experience with PCR reactions. "[I]t is imperative when attempting to prove lack of enablement to show that one of ordinary skill in the art would be unable to make the claimed invention without undue experimentation." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998). Nevertheless, as discussed in the accompanying

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Declaration of Dr. Feinberg, by the time such experiments were terminated, amplification of the target had been shown.

B. Gen-Probe's Contention that Amplification Using Qβ Replicase is Not Enabled

Gen-Probe also asserts that the specification does not enable amplification of a target polynucleotide using Qβ replicase. During the related litigation, Gen-Probe further supported this argument with the expert report of Dr. Fred R. Kramer. Yet, Gen-Probe's assertions are belied by one of Dr. Kramer's own patents, U.S. Patent No. 5,112,734, which indicates that Qβ replicase can be used to amplify a target polynucleotide. (See Figure 3; col. 8, lines 8-35; and claims 24 and 46.)[1] Moreover, nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971); *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. *In re Chilowsky*, 229 F.2d 457, 461 (C.C.P.A. 1956); *Gould v. Quigg*, 822 F.2d 1074, 1078 (Fed. Cir. 1987).

The present claims are intended to be directed to the use of operable techniques for amplifying target polynucleotides. If a particular enzyme does not function for that purpose in a particular environment, it does not result in target amplification and is not within the scope of the claims. Even if some embodiments within the scope of a patent claim may not work, that is not fatal to enablement as long as the number of such embodiments is not so large that undue experimentation would be required to determine which embodiments work and which do not. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984).

Notwithstanding the Patent Owner's disagreement with Gen-Probe's contentions, to

[1] A copy of U.S. Patent No. 5,112,734 is attached hereto.

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render moot any contention that the claims must encompass the amplification of a target polynucleotide using Qβ replicase that might not work, the Patent Owner is amending claims 5, 11, 30, and 36 to eliminate reference to Qβ replicase. If, as Gen-Probe contends, Qβ replicase cannot be used for target amplification, then it is simply not within the scope of claims requiring successful target amplification.

II. Entitlement of the Claims to a Filing Date of December 21, 1987

Gen-Probe contends that the '338 patent is not entitled to a filing date of December 21, 1987, and therefore the claims are anticipated pursuant to 35 U.S.C. § 102(b) in view of the August 23, 1989 publication of the Patent Owner's European counterpart application. (G-P Contentions, ¶¶ 81-141, 278-309.) Gen-Probe makes several arguments in support of that contention, which are presented in considerable detail in its Memorandum of Contentions of Fact and Law. Though Gen-Probe's arguments are briefly summarized here, the Patent Owner urges a full review of paragraphs 81-141 and 278-309 of Gen-Probe's Contentions for a complete recitation of its arguments and for the authority upon which Gen-Probe relies.

A. Gen-Probe's Contentions and Vysis' Response

1. Gen-Probe contends that the '338 patent is not entitled to a December 21, 1987 filing date because claims presented in intervening applications were not supported by the disclosure of prior applications in the chain. (G-P Contentions, ¶¶ 285, 293, 297.)

The Patent Owner contends that the law is well settled that the claims that are actually pending in an intervening application need not themselves have been supported by the disclosure of the original application in the manner required by 35 U.S.C. § 112, first paragraph. *KangaROOS v. Caldor*, 228 U.S.P.Q. 32, 34 (Fed. Cir. 1985) (holding that the critical issue of law was support for the claims of the grandchild application that issued as the patent in the original grandparent disclosure and not whether the claims of the intervening parent application were supported by the grandparent application). The relevant inquiry is whether there was a

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continuous chain of copending applications that name at least one common inventor, contain a disclosure of the subject matter now claimed, and make reference to the earlier applications in the chain, which there clearly was.

2. Gen-Probe contends that the '338 patent is not entitled to a December 21, 1987 filing date because the Patent Owner allegedly failed to maintain consonance with a restriction requirement made during prosecution. G-P Contentions, ¶¶ 286, 294, 298, 303.) In support of that contention, Gen-Probe cites *Gerber Garment Technology Inc. v. Lectra Systems*, 16 U.S.P.Q.2d 1437, 1440-41 (Fed. Cir. 1990).

There is no prohibition on the nature of claims that may be presented in continuing applications following a restriction requirement. Indeed, the case law upon which Gen-Probe relies refutes its own contention that lack of consonance with a restriction requirement has any impact on entitlement to an earlier application filing date under 35 U.S.C. § 120. In *Gerber*, the consequence of failing to maintain consonance with the restriction requirement was loss of the protection afforded by the third sentence of 35 U.S.C. § 121, under which patents issuing as the result of a restriction requirement may not be used as a reference against each other *for double patenting* analyses. *Gerber* itself makes clear that failure to maintain consonance does *not* destroy entitlement to an earlier application filing date under 35 U.S.C. § 120.

3. Gen-Probe contends that "the certificate of correction obtained by Vysis after the issuance of the '338 patent, changing the claim of priority from U.S. patent application 08/400,657 to U.S. patent application 08/124,826 is invalid and ineffective because that certificate of correction could not and did not amend the '080 application itself. The certificate therefore did not change the effective date of the '080 application under the literal language of 35 U.S.C. § 120, which requires that the application for the patent be amended. *See Sampson v. Ampex Corp.*, 333 F.Supp. 59, 63 (S.D.N.Y. 1971)." (G-P Contentions, ¶ 300.)

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The Patent Owner contends that Gen-Probe's argument is flagrantly at odds with prior PTO decisions, such as *In re Schuurs*, 218 U.S.P.Q. 443 (Commr. Pats. 1983), and *In re Lambrech*, 202 U.S.P.Q. 620 (Commr. Pats. 1976), clearly indicating that a certificate of correction may be used to insert a necessary reference to an earlier filed application. A certificate of correction by definition results in the correction of the issued patent. If the PTO disagrees and is of the view that any such amendment should be made by way of reissue rather than certificate of correction, the Patent Owner proffers the appropriate corresponding amendments in this reissue application.

4. To perfect its claim to priority under 35 U.S.C. § 120, the Patent Owner amended three abandoned applications in the chain of applications it relies upon for support to the filing date of December 21, 1987 to make specific reference to earlier applications. Gen-Probe contends that the post-abandonment amendments were legally invalid, null, and void because Vysis did not revive those applications pursuant to 35 U.S.C. § 133 and 37 C.F.R. § 1.137(a) or pursuant to 35 U.S.C. § 41(a)(7) and 37 C.F.R. § 1.137(b) and did not make the amendments in good faith and with honesty. (G-P Contentions, ¶ 284.)

The Patent Owner contends that the law permits amendment of an abandoned application for the purpose of making a specific reference to an earlier filed application in accordance with 35 U.S.C. § 120. *See Sampson v. Commissioner of Patents and Trademarks*, 195 U.S.P.Q. 136 (D.D.C. 1976). Indeed, here the PTO entered Vysis' amendments to the abandoned applications, citing *Sampson*. Nonetheless, in the event the PTO now reads *Sampson* as limiting the amendment to intermediate abandoned applications to include technical information (i.e., specific reference to earlier applications) only to situations in which that information would allow *reissue* of a patent if the amendments were applied to the application upon which the patent originally issued, the Patent Owner again proffers appropriate corresponding amendments to the abandoned '468, '749, and 826 applications in connection with this reissue proceeding to perfect its right to an effective filing date of December 21, 1987.

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5. Gen-Probe contends that "the certificate of correction obtained by Vysis after the issuance of the '338 patent, changing the claim of priority from U.S. patent application 08/400,657 to U.S. patent application 08/124,826 is invalid because Vysis' request for the certificate of correction did not meet the statutory requirements for a certificate of correction under 35 U.S.C. § 255. . . . The '080 application's claim of priority to the '826 application was not 'a mistake of a clerical or typographical nature, or of minor character.'" (G-P Contentions, ¶ 301.)

The Patent Owner contends that the authorities are clear that a certificate of correction may be used to perfect a claim to priority under 35 U.S.C. § 120, and such cases have explicitly held that omission of a reference to an earlier application on which priority is based is a mistake "of a minor character" which is correctable by certificate of correction. *See In re Lambrech*, 202 U.S.P.Q. at 622. Gen-Probe alleges that the mistake was not inadvertent, citing a series of cases in which deliberate actions were taken in earlier prosecution which could not thereafter be corrected by reissue. The fact that efforts were made to assert this right and that they were deficient due to errors in the identification of the serial numbers for certain of the intervening applications does not convert the error into an uncorrectable deliberate act. Indeed, in P.J. Federico's "Commentary on the New Patent Act," (reprinted at 75 J. Pat. Trademark Off. Soc'y 161, 180 (1993), he specifically notes "it is difficult to imagine a situation in which this right would be deliberately waived."

6. Gen-Probe also alleges that "if the '080 application's claim of priority to the '826 application was 'a mistake of a clerical or typographical nature, or of minor character,' such mistake did not occur in good faith. The applicant's overall course of conduct with respect to the prosecution of applications for the '338 patent, particularly after abandonment of the '505 application, demonstrates the applicant's lack of good faith." (G-P Contentions, ¶ 301.) While the Patent Owner contends that the abandonment of the '505 application was not intentional, that abandonment is irrelevant to the issue of the entitlement of the claims of the filing date of

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December 21, 1987 pursuant to 35 U.S.C. § 120. As noted above, the relevant inquiry is into whether there was a continuous chain of copending applications naming at least one common inventor and containing a disclosure of the subject matter now claimed, which there clearly was.

7. Gen-Probe contends that "no claim of the '080 application is disclosed in the '826 application in the manner provided by the first paragraph of 35 U.S.C. § 112, as required by 35 U.S.C. § 120. . . . Adequate 'disclosure' under sections 120 and 112 with respect to an invention claimed in a prior application may not be accomplished solely by a conclusory boilerplate 'incorporation by reference.' . . . Conclusory boilerplate 'incorporation by reference' is particularly ineffective for purposes of section 120 when the earlier application was filed in response to a restriction requirement by the PTO, for such incorporation violates principles of consonance, . . . and where the inventors on the two applications are not the same." (G-P Contentions, ¶ 302 (citations omitted).)

The Patent Owner contends that once again, Gen-Probe is wrong as a matter of law. Incorporation of the disclosure of a parent application by reference is sufficient for compliance with 35 U.S.C. § 120. *See, e.g.*, M.P.E.P. § 608.01(p); *Ex parte Maziere*, 27 U.S.P.Q.2d 1705 (Bd. Pat. App. & Int. 1993).

Accordingly, all of Gen-Probe's arguments that the claims are not entitled to a filing date of December 21, 1987 are unavailing. The Patent Owner believes that all of the claims of the '338 patent and the reissue application are entitled to an effective filing date of December 21, 1987, because the claims satisfy each requirement of 35 U.S.C. § 120 with respect to U.S. Patent Application Serial Number 07/136,920, from which the '338 patent and the reissue application claim priority.

III. Gen-Probe's Arguments Based on Prior Art

In the related litigation, Gen-Probe has also contended that the claims of the '338 patent are anticipated and/or obvious in view of certain prior art references. (See G-P Contentions,

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¶¶ 142 - 176.) Those arguments are largely duplicative of the arguments Gen-Probe raised in the Protest it filed in this reissue proceeding. Gen-Probe has, however, newly identified several references that it did not rely upon in its Protest or that are not already otherwise of record in this reissue proceeding. Gen-Probe has categorized those references into three general groups: (i) art concerning isolation of target polynucleotides from a sample by capture on a solid support; (ii) art disclosing "amplification of target polynucleotides, or target-like polynucleotides;" and (iii) art disclosing "the combination of target capture on a solid support with amplification of the isolated polynucleotide," as well as the motivation to combine target capture with amplification.

The Patent Owner believes that the newly-identified references are either (i) cumulative to art already of record in this proceeding; (ii) not prior art; or (iii) do not render the properly-construed claims of the pending reissue application unpatentable under 35 U.S.C. §§ 102 or 103. For example, the Chu et al., *Nucleic Acids Research* publication relied on by Gen-Probe (G-P Contentions, ¶ 155) is cumulative to U.S. Patent No. 4,957,858 to Chu et al., cited by Gen-Probe in its Information Disclosure Statement of March 26, 2001. The Kourilsky patent and the Manning publication cited by Gen-Probe (G-P Contentions, ¶ 154) disclose *signal* amplification techniques (the use of enzyme labels to catalyze numerous observable chemical reactions), not techniques involving amplification of a target polynucleotide as recited in the pending claims. Similarly, the Lizardi Invention Report and Record, dated February 8, 1985, and the Lizardi manuscript submitted for publication on December 18, 1987 relied upon by Gen-Probe (G-P Contentions, ¶ 176) do not disclose amplification of a target polynucleotide as claimed in the pending reissue application, and also are not prior art within the meaning of § 102.[2] Finally, the Feix and Pollet publications relied upon by Gen-Probe (G-P Contentions, ¶¶ 173-175) describe a tedious multi-step purification of a certain species of RNA that involves chromatography. Feix

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[2] Paragraph 176 of Gen-Probe's Contentions erroneously describes the Lizardi manuscript has having been submitted for publication on December 18, 1981. The document actually states that it was submitted on December 18, 1987.

and Pollet do not teach a step of substantially separating the support and bound target polynucleotide from a sample of the sort now claimed, or the use of probes, or detection methods, or kits, as required by the pending claims. Accordingly, none of the newly-identified art renders the pending claims unpatentable.

Respectfully submitted,

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By: Jean Burke Fordis
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Dated: February 21, 2002

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